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CONNECTOR AND A DISPOSABLE ASSEMBLY UTILIZING SAID CONNECTOR ;

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ABSTRACT:

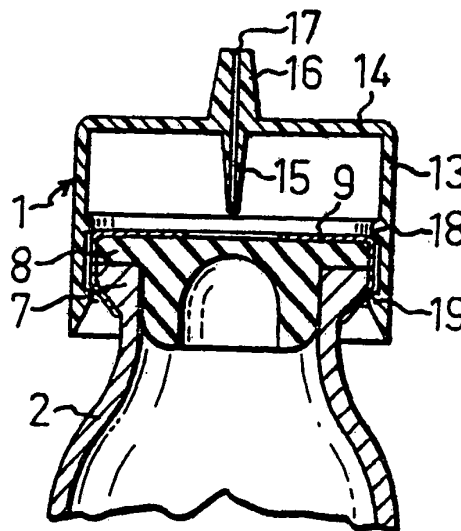
A disposable assembly comprises a drug container (2) having at one end an opening which is surrounded by an outwardly directed flange (7). A connector (1) has a sleeve (13) which is closed (14) at one end and open at its opposite end to receive the flanged end of the drug container as a plunger. Positioning means (18,19) provided within the sleeve and cooperating with the flange define an inserted and a retracted position of said sleeve relative to the flanged end of the drug container. A piercing member (15) provided at the closed end of the sleeve is directed towards the open sleeve end. A connecting member (16) provided at the closed sleeve end is directed opposite to said piercing member (15) and communicating therewith by means of a through passage (17).

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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/SE87/00398 <b>(22) International Filing Date:</b> 7 September 1987 (07.09.87) <b>(31) Priority Application Numbers:</b> 8603928-6 8605259-4 <b>(32) Priority Dates:</b> 18 September 1986 (18.09.86) 9 December 1986 (09.12.86) <b>(33) Priority Country:</b> SE <b>(71) Applicant (for all designated States except US):</b> AKTIEBOLAGET LEO [SE/SE]; Box 941, S-251 09 Helsingborg (SE). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only) :</b> MALMBORG, Bengt, Eber [SE/SE]; Skånegatan 47, S-252 52 Helsingborg (SE). <b>(74) Agent:</b> THYLÉN, Eva; Aktiebolaget Leo, Box 941, S-251 09 Helsingborg (SE).		<b>(81) Designated States:</b> AT, AT (European patent), AU, BE (European patent), CH, CH (European patent), DE, DE (European patent), DK, FI, FR (European patent), GB, GB (European patent), HU, IT (European patent), JP, KR, LU, LU (European patent), NL, NL (European patent), NO, SE, SE (European patent), US.  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> CONNECTOR AND A DISPOSABLE ASSEMBLY UTILIZING SAID CONNECTOR		

**(57) Abstract**

A disposable assembly comprises a drug container (2) having at one end an opening which is surrounded by an outwardly directed flange (7). A connector (1) has a sleeve (13) which is closed (14) at one end and open at its opposite end to receive the flanged end of the drug container as a plunger. Positioning means (18, 19) provided within the sleeve and cooperating with the flange define an inserted and a retracted position of said sleeve relative to the flanged end of the drug container. A piercing member (15) provided at the closed end of the sleeve is directed towards the open sleeve end. A connecting member (16) provided at the closed sleeve end is directed opposite to said piercing member (15) and communicating therewith by means of a through passage (17).

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CONNECTOR AND A DISPOSABLE ASSEMBLY  
UTILIZING SAID CONNECTOR

The present invention relates generally to the handling of toxic substances and drugs, especially pharmacologically active, hazardous substances.

5 More particularly, the invention relates to a connector for a container having at one end an opening which is closed by means of a pierceable closure and which is surrounded by an outwardly directed flange, and having a plunger movable within the container and closely engaging the container inner wall, a toxic  
10 substance, e.g. a drug component, being enclosed between said plunger and said closure, for mixing with a liquid prior to administration.

The invention also relates to a disposable assembly comprising said container, said connector and, optionally, a container for the liquid, interconnected  
15 to form a unit.

Many different types of pharmaceuticals are hazardous and risky to handle. Medical staff exposed to these drugs when preparing mixtures for administration to patients must take many precautions to avoid  
20 the risks associated with the handling of the drugs. In view hereof, there is urgent need for devices which reduce the staff's exposure to such drugs and which could simplify their routines to a considerable extent.

25 Cytostatic drugs as used for the treatment of cancer are one type of drug which requires safe handling. These drugs are often supplied by the manufacturer in the form of a dry powder in a sealed glass vial together with an ampoule containing the solvent, for  
30 example water or an aqueous solution, for dissolving the drug. The most important steps which the medical staff must take in order to prepare a drug solution

ready for administration, such as injection, to the patient, may be summarised as follows:

- (1) opening an ampoule containing the solvent and drawing the solvent from the ampoule up into a syringe;
- 5 (2) carefully emptying the solvent to avoid excess pressure from the syringe into a vessel containing the dry cytostatic agent;
- (3) drawing the dissolved drug, after a period of dissolution, carefully up into a syringe intended  
10 for the administration.

It is recommended that this preparation be carried out in a fume cupboard and a well-aerated room, and also that the work be done by specially trained personnel.

The preparation technique described also involves  
15 a risk of contamination, incorrect dosing and, furthermore, a risk that the wrong components are mixed, especially if mixing is effected by untrained staff members.

Many attempts at solving these problems have  
20 been made, for example by supplying the syringe and the ampoule connected together by means of a special connector. Examples of such combinations are disclosed in, inter alia, US-A-3,826,260, WO-A1-86/05683 and DE-A-1,766,152.

25 The combination according to US-A-3,826,260 comprises a syringe containing a solvent, a vial containing a drug, and a connector including a cannula. The syringe is of the type having a neck and a seal, the seal being held in position by a specially designed sleeve of reduced diameter. The vial is of  
30 similar construction and has a seal and a specially designed sleeve. The cannula is mounted in a support which is movable from an outer to an inner position on the first-mentioned sleeve. Although this combination  
35 is intended for mixing a drug with a solvent, mixing takes place in the vial, not in the syringe. The specially designed sleeve of the syringe and the vial for con-

nection with the cannula support and the connector, respectively, make this combination complicated and fairly long. Furthermore, the combination does not permit connection to an optional means of administration.

WO-A1-86/05683 discloses a device for transferring two components of a drug between two containers and to the patient, respectively. The device comprises a connector having a single or double cannula. Two sleeve-shaped supports can be screwed onto the connector to protect the cannula. Different types of containers are insertable through the supports to a position in which the cannula ends pierce the seals at the container ends. In this manner, the component of one container can be transferred to the component of the other container. The device requires further protective means for the cannula ends in the event that the supports are not attached to the connector. However, also these protective means must be pierceable by the cannula points. When this device is to be used, the supports are interconnected with a connector, whereupon two containers, each with one component, can be interconnected via the cannula by inserting them into the supports in a direction toward one another. After the component of one container has been transferred to the other container, the empty container is removed and replaced by a container having a retractable plunger, and the two components which are now mixed, are transferred to the latter container prior to administration.

DE-A1-1,766,152 discloses a device for converting a single-compartment syringe into a two-compartment syringe. The device comprises two sleeves, each having an open end and a closed end. Extending through the sealed end of one sleeve is a double-pointed cannula, and this sealed end also has an external thread for threaded engagement with an internal thread in the open end of the other sleeve. Each sleeve has a container

with a seal immediately adjacent each cannula point. When the device is to be used, the sleeves are screwed together and the cannula with its two points pierces the seals of the containers. The components in the  
5 containers can now be mixed by retracting a plunger in one of the containers. Finally, the sleeves are unscrewed from one another to provide a syringe ready for administration of the mixed drug.

The object of the present invention is to provide  
10 a connector which is intended for containers with flanged ends and which satisfies the requirements stipulated for the handling of poisonous drugs, viz. that the staff handling the drug must not be exposed thereto during any phase of the handling, and that  
15 no contamination must occur. In addition, the connector should be simple, inexpensive and comprise but few parts, such that it can form part of a disposable assembly. Furthermore, the connector must be connectible to different means of administration.

This object is achieved, according to the present  
20 invention, in that the connector is in the form of a sleeve which is closed at one end, which is open at its opposite end to receive the flanged container end as a plunger, and which has internal positioning means cooperating with the flange and adapted to define  
25 an inserted and an extracted position of said sleeve relative to the flanged end of the container; a piercing member provided at the sealed end of the sleeve and directed towards the open sleeve end and adapted to  
30 pierce the closure of the container upon displacement of the sleeve from the retracted to the inserted position; and a connecting member provided at the closed sleeve end and directed opposite to said piercing member and connected therewith by means of a through passage,  
35 for connection of the substance or drug container first to a liquid container for sucking up liquid in said substance or drug container by retraction of the plunger therein, and then to a means for administration of the substance/liquid mixture.

The connector thus is a single element which cooperates directly with the outwardly directed flange on the container. Because of the positioning means according to the invention, the container can be safely moved between the two positions relative to the sleeve whereby, in particular, resealing of the container can be effected during the mixing of the drug component and the liquid by displacing the sleeve from the inserted to the extracted position in which the piercing member is outside the closure which thus can reseal the opening in the container end.

The positioning means may be in the form of at least one inwardly directed bead on the inner side of the sleeve. In an especially advantageous embodiment, the connecting member also constitutes a piercing member for a pierceable closure of the liquid container. In this embodiment, the connector preferably has a sleeve extension extending in the same direction as the connecting member, for guiding the liquid container toward the connecting member. Internal positioning means may also be arranged in the sleeve extension to define an inserted and a retracted position of the extension relative to the liquid container.

Connection to the means of administration is simplified considerably if the extension is designed for breakaway removal from the sleeve.

The invention comprises not only the connector, but also a combination of the connector and the said drug container, as well as a combination of the connector, the said drug container and the said liquid container.

The invention will be described in more detail below, reference being had to the accompanying drawings. Fig. 1 illustrates a preferred embodiment of the disposable assembly according to the invention, comprising a drug container, a connector, and a liquid container.



Fig 2 is an exploded perspective view of the parts comprised by the disposable assembly according to Fig. 1. Fig. 3 is a longitudinal section of a connector according to the invention. Fig. 4 is a perspective view of the connecting and piercing members of the connector. Figs. 5 and 6 are longitudinal sections illustrating the retracted and inserted positions of the connector according to Fig. 3 relative to the containers according to Figs. 1 and 2. Fig. 7 illustrates the operating sequence during use of the disposable assembly according to Fig. 1. Figs. 8 and 9 illustrate an alternative connector in, respectively, a retracted and an inserted position relative to a drug container. Fig. 10 illustrates the operating sequence during use of the connector according to Figs. 8 and 9.

The disposable assembly shown in Figs. 1 and 2 comprises a connector 1, a container 2 for a drug component and a liquid container 3. The container 3 is a conventional vial having a neck and a flange 4 around the neck opening, a closure 5 in the form of, for example, a rubber stopper, and a cap 6 having a central hole and intended to keep the closure 5 in position in the neck opening by engaging the flange 4. Also the container 2 has a neck provided with a flange 7, a closure 8 and a cap 9. A plunger 10 is displaceable within the container 2 by means of a plunger rod 11, insertion of the plunger 10 being simplified by a finger grip 12 on the container 2. The plunger 10 and the plunger rod 11 are disconnectible from one another by means of a threaded connection.

In manufacturing the disposable assembly according to Fig. 1, a drug component is first introduced into the container 2, with the plunger 10 partly inserted therein, whereupon the container 2 is closed by means of the closure 8 which may be a stopper suitable for freeze-drying and is secured in position by means of the cap 9. The liquid to be admixed to the drug

component of the container 2 is filled into the container 3 which then is closed by means of the closure 5 and the cap 6. After that, the containers 2 and 3 are interconnected by means of the connector 1, the container 2 and also the container 3 being fixed in a retracted position relative to the connector 1 by cooperation between the flange 4, 7 and internal positioning means in the connector 1.

The embodiment of the connector 1 as illustrated in Fig. 3, which preferably is made of plastic, comprises a sleeve 13 having an open end and another end closed by means of a partition 14. Extending from the end of the partition 14 toward the open end of the sleeve 13, is a piercing member 15 in the form of a truncated cone. A connecting member 16 extends from the partition 14 in the opposite direction to the piercing member 15. The connecting member 16 is conical along the major part of its length and thus can constitute one part of a so-called luer coupling. A through passage 17 communicates the piercing member 15 with the connecting member 16 and thus extends also through the partition 14. More particularly, the passage 17 opens into the free end of the piercing member 15 and the connecting member 16. A sharp cutting edge is formed around the opening of the passage 17 into the piercing member 15. A similar sharp cutting edge is formed around the opening of the passage 17 into the connecting member 16 which thus also constitutes a piercing member. The sleeve 13 has a first inner bead 18 approximately on a level with the point of the piercing member 15. A second bead 19 is formed at the open end of the sleeve 13.

The connector 1 shown in Fig. 3 furthermore has an extension 20 of the sleeve 13, said extension 20 extending in the same direction as the connecting member 16. Also the extension 20 is sleeve-shaped,

although not connected with the sleeve 13 along its entire circumference, but only within limited portions 21. Like the sleeve 13, the extension 20 furthermore has an inner bead 22 approximately on a level with the point of the connecting member 16, as well as a bead 23 at its open outer end.

Fig. 4 illustrates another embodiment of the connecting member 16. Here, the portion of the connecting member 16 nearest the partition 14 is cylindrical and delimited from the conical portion by a collar 24. Axial grooves 25 extend along the cylindrical portion from the partition 14 and past the collar 24.

In Fig. 5, the connector 1 is in its retracted position relative to both the container 2 and the container 3. More particularly, the flange 7 of the container 2 is accommodated by the space defined by the inner side of the sleeve 13 and the beads 18 and 19. The container 2 is insertable into this position past the bead 19 because the material of the sleeve 13 is resilient. Similarly, the container 3 and its flange 4 are accommodated by the space which is formed in the extension 20 between the beads 22 and 23. In the positions indicated, the point of the piercing member 15 lies outside the rubber stopper 8 in the neck of the container 2, and the point of the connecting member 16 lies outside the closure 5 in the neck of the container 3.

In order to establish communication between the containers 2 and 3 via the passage 17, the containers 2 and 3 are displaced simultaneously or consecutively toward one another into the position shown in Fig. 6, in which the flange 7 lies in the space within the sleeve 13 which is delimited outwardly by the bead 18, and the flange 4 lies in the space in the extension 20 which is delimited outwardly by the bead 22. When the containers 2 and 3 are moved toward one another, their flanges act as plungers in the sleeve

13 and the extension 20, respectively, although a not inconsiderable force is required to effect the movement past the bead 18 and 22, respectively, so that such displacement cannot be made unintentionally.

5 The displacement past the beads 18 and 22 is possible because the connector 1 is made of some suitable resilient material, such as plastic. During the said displacement movement, the piercing member 15 will pierce the closure 8, and the combined connecting and piercing

10 member 16 will pierce the closure 5 so that the containers 2 and 3 will communicate with one another via the passage 17. In this manner, liquid can be transferred from one container to the other. If the connecting member 16 has the shape shown in Fig. 4,

15 the collar 24 will lie, after the displacement, on the inner side of the closure 5, the grooves 25 establishing an air communication into the liquid container 3 to facilitate emptying thereof.

All of the steps comprised by an operating sequence

20 during use of the assembly according to Fig. 1 are schematically shown in Fig. 7. In the starting position A, the containers 2 and 3 are in the retracted position relative to the connector 1, as shown also in Figs. 1 and 5. In the next step B, the containers 2 and

25 3 are simultaneously or consecutively displaced toward one another, whereby the closures 5 and 8 are pierced and communication is established between the containers 2 and 3, as also shown in Fig. 6. In a subsequent

30 step C, the plunger 10 in the container 2 is retracted, whereby the liquid in the container 2 is transferred by suction to the container 2. In step D, the sleeve 13 then is moved into its retracted position relative to the container 2, whereby the piercing member 15

35 is retracted from its position piercing the closure 8. In this manner, the drug component and the liquid can be mixed in the container 2 without any risk that the operator is exposed to the mixture since the closure

10

8 closes itself completely at the point where it has previously been pierced by the piercing member 15.

When the mixture within the container 2 is ready for administration, the extension 20 is removed in step E from the sleeve 13 by breaking away the portions 21. Before then, the container 3 has been pushed into its retracted position relative to the extension 20, or been completely removed therefrom.

After the extension 20 has been broken away, the connecting member 16 is exposed to be connected in step F to some suitable means for administration of the mixture in the container 2. This means may be, for example, a cannula, a catheter, a probe, or an infusion device having a connecting member complementary to the connecting member 16. After these connecting members have been connected together, the sleeve 13 is again moved into its inserted position relative to the container 2, as shown in step G of Fig. 7. Administration is then effected by inserting the plunger 10 into the container 2.

Figs. 8 and 9 illustrate an alternative embodiment of the connector 1 in which the extension 20 is missing and in which there is no sharp cutting edge for piercing on the connecting member 16. Fig. 8 shows the connector 1 in its retracted position relative to the container 2, and in Fig. 9 the connector is shown in its inserted position relative to the container 2, the piercing member 15 having pierced the closure 8 so that communication is established, via the passage 17, between the container 2 and the free end of the connecting member 16.

The handling of the connector according to Figs. 8 and 9 is illustrated in Fig. 10. In a first step A a conventional ampoule containing a predetermined amount of a solvent, is broken. In step B, an external means 26 is attached to the connecting member 16 of the connector. The external means 26 is a cannula. A

needle protector 27 which may be used for protecting the cannula against contamination and physical damage, is also removed. In step C, the connector 1 is moved into the inserted position relative to the container 2, and communication is established between the cannula 26 and the container 2 via the passage 17. In a subsequent step D, solvent is sucked from the ampoule into the drug container 2 by retracting the plunger 10 in the container 2. After that, the container 2 is closed in step E by moving the connector 1 into its retracted position in which the piercing member 15 does not pierce the closure 8 of the container 2. In position E, a drug in solid form can be left for dissolution. The cannula 26 may also be removed and replaced by some other means for administration. When the device is to be used, the connector 1 is again moved, in step F, from the retracted to the inserted position so that communication is established between the container 2 and the means for administration.

Although the device according to the invention has been described above in its application to dry, cytostatic drugs, a person skilled in the art will appreciate that also other toxic substances, e.g. other drugs which may be in liquid or dry form and which have other pharmacological effects, can be enclosed within the container 2.

Modifications of the embodiments described above are, of course, conceivable. Thus, the beads 19, 22 and 23 can be replaced by other positioning means, while the bead 18 preferably is a continuous bead. Moreover, the extension 20 may serve its function without being sleeve-shaped, and to facilitate its removal from the sleeve 13 it is also possible to reduce the thickness of the material.

Preferred embodiments of the invention have been described above and illustrated in the drawings, but it will be appreciated that these descriptions and

drawings merely are intended to illustrate the basic features of the invention and are not intended to restrict the scope of the invention and the appended claims.

## CLAIMS

1. A connector for a container (2) having at one end an opening which is closed by means of a pierceable closure (8) and which is surrounded by an outwardly directed flange (7), and having a plunger (10) movable  
5 within the container and closely engaging the container inner wall, c h a r a c t e r i s e d by a sleeve (13) which is closed (14) at one end, which is open at its opposite end to receive the flanged container (2) end, and which has internal positioning means  
10 (18, 19) cooperating with the flange (7) and adapted to define an inserted and an extracted position of said sleeve relative to the flanged end of the container; a piercing member (15) provided at the closed end of the sleeve and directed towards the open sleeve  
15 end and adapted to pierce the closure (8) of the container upon displacement of the sleeve from the retracted to the inserted position and a connecting member (16) provided at the closed sleeve end and directed opposite to said piercing member (15) and  
20 communicating therewith by means of a through passage (17).

2. A connector as claimed in claim 1, c h a -  
r a c t e r i s e d in that said positioning means  
(18, 19) comprise at least one inwardly directed bead  
25 (18).

3. A connector as claimed in claim 1 or 2, c h a -  
r a c t e r i s e d in that said connecting member  
(16) also constitutes a piercing member for a pierceable  
closure (5) of a liquid container (3).

30 4. A connector as claimed in claim 3, c h a -  
r a c t e r i s e d by a sleeve extension (20) extending in the same direction as said connecting member (16), for guiding the liquid container (3) toward said connecting member.



5 5. A connector as claimed in claim 4, c h a -  
r a c t e r i s e d by internal positioning means  
(22, 23) in the sleeve extension (20) for defining  
an inserted and a retracted position of said exten-  
sion relative to the liquid container (3).

6. A connector as claimed in claim 4 or 5, c h a -  
r a c t e r i s e d in that said extension (20) is  
adapted to be broken away from the sleeve (13).

10 7. A connector as claimed in any one of claims  
1-6, c h a r a c t e r i s e d by at least one axial  
groove (25) in the inner part of said connecting mem-  
ber (16).

15 8. A connector as claimed in claim 7, c h a -  
r a c t e r i s e d in that said connecting member  
(16) has an outer part in the form of a truncated  
cone, into the narrow end of which the through passage  
(17) opens and forms a sharp edge, and an inner sub-  
stantially cylindrical part in which the axial groove  
or grooves (25) are located.

20 9. A disposable assembly, c h a r a c t e r i s e d  
by a container (2) having at one end an opening which  
is closed by means of a pierceable closure (8) and  
which is surrounded by an outwardly directed flange  
(7), and having a plunger (10) movable within the  
25 container and closely engaging the container inner  
wall, a drug component being enclosed between said  
plunger and said closure, for mixing with a liquid  
prior to administration, and a connector (1) to said  
container, having a sleeve (13) which is closed (14)  
30 at one end, which is open at its opposite end to receive  
the flanged end of the container (2) as a plunger,  
and which has internal positioning means (18, 19)  
cooperating with the flange (7) and adapted to define  
an inserted and a retracted position of said sleeve  
35 relative to the flanged end of the container, a piercing  
member (15) provided at the closed end of the sleeve  
and directed towards the open sleeve end and adapted  
to pierce the closure (8) of the container upon displace-

ment of the sleeve from the retracted to the inserted position, and a connecting member (16) provided at the closed sleeve end and directed opposite to said piercing member (15) and communicating therewith by means of a through passage (17), for connection of the drug container first to a liquid container (3) for sucking up liquid in said drug container (2) by retraction of the plunger (10) therein, and then to a means for administration of the drug component/liquid mixture.

10. A disposable assembly, characterized by a container (2) having at one end an opening which is closed by means of a pierceable closure (8) and which is surrounded by an outwardly directed flange (7), and having a plunger (10) movable within the container and closely engaging the container inner wall, a drug component being enclosed between said plunger and said closure, for mixing with a liquid prior to administration; a second container (3) for said liquid, said container having at one end an opening which is closed by a pierceable closure (5) and which is surrounded by an outwardly directed flange (4); and a connector (1) for connection of said drug container (2) and said liquid container (3), said connector having a sleeve (13) which is closed (14) at one end, which is open at its opposite end to receive the flanged end of the drug container as a plunger, and which has internal positioning means (18, 19) cooperating with the flange and adapted to define an inserted and a retracted position of said sleeve relative to the flanged end of the drug container, a piercing member (15) provided at the closed end of the sleeve and directed towards the open sleeve end and adapted to pierce the closure (8) of the drug container upon displacement of the sleeve from the retracted to the inserted position, a connecting member (16) provided at the closed sleeve end and directed opposite to said piercing member (15) and communicating therewith

16

by means of a through passage (17), for connection  
of the drug container (2) first to the liquid container  
(3) for sucking up liquid in said drug container by  
retraction of the plunger therein, and then to a means  
for administration of the drug component/liquid mixture,  
and an extension (20) of said sleeve (13), said extension  
extending in the same direction as said connecting  
member (16) and adapted to guide said liquid container  
toward said connecting member (16).

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Fig.1

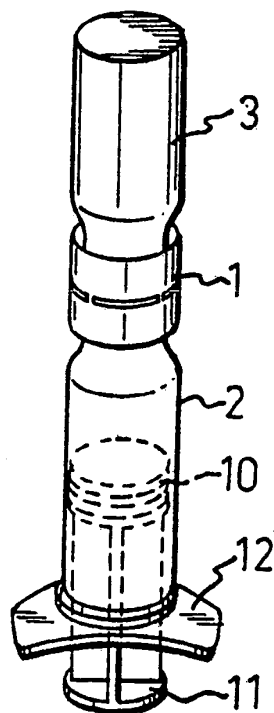
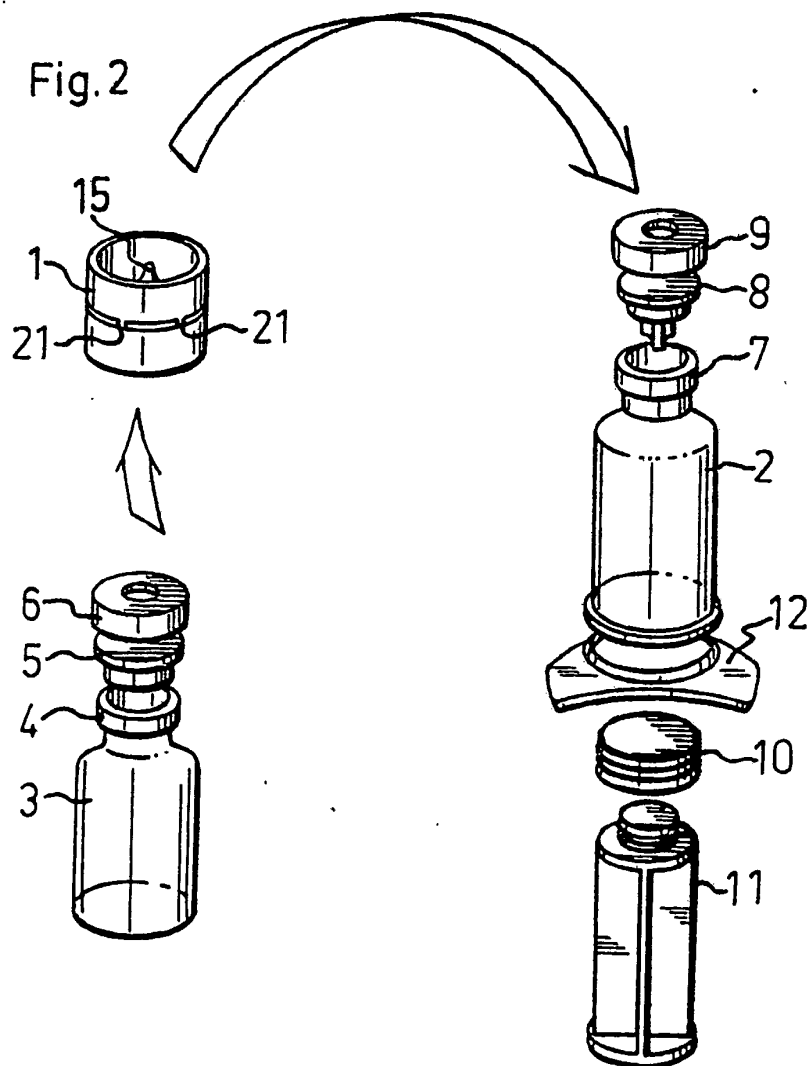


Fig.2



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Fig.3

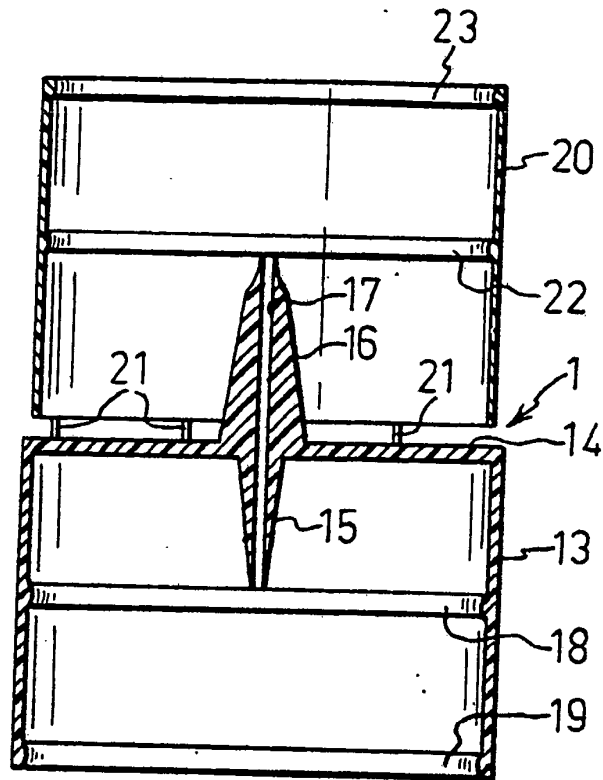


Fig.4

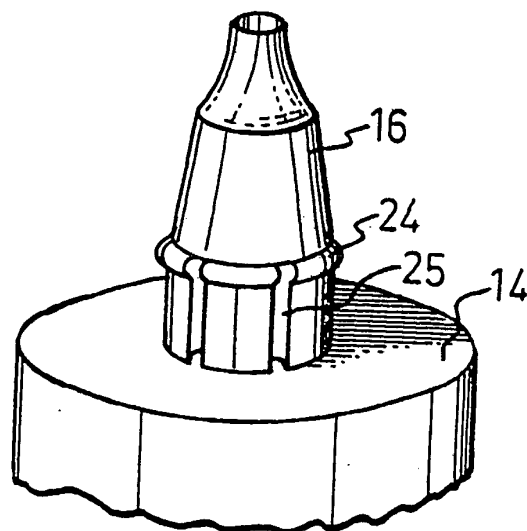


Fig.5

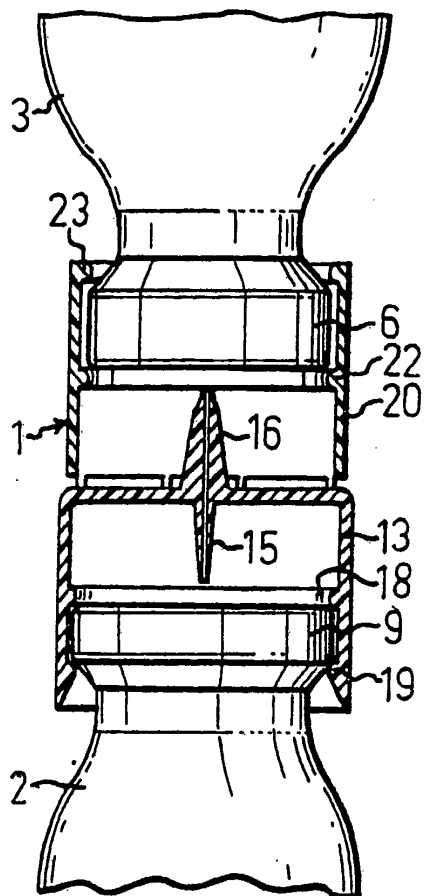


Fig.6

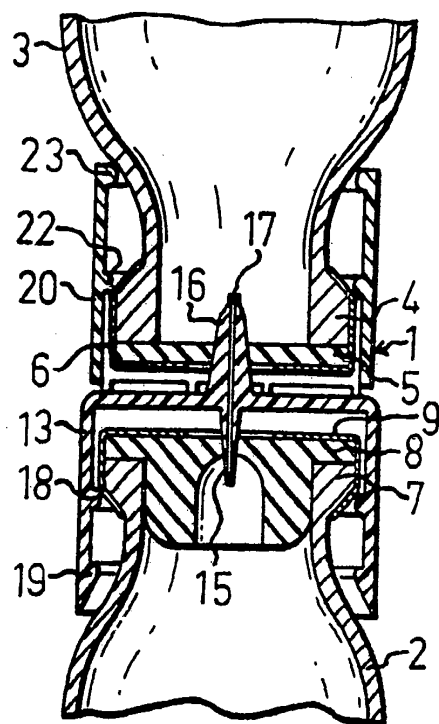


Fig.8

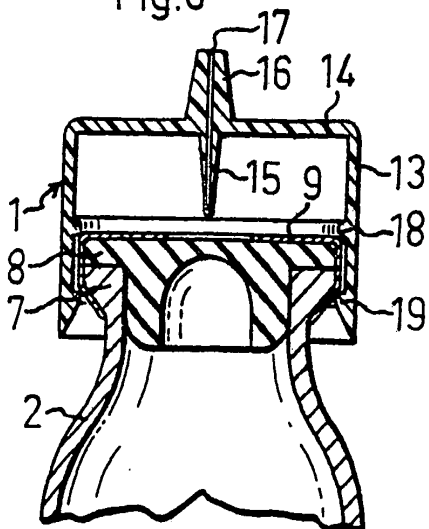
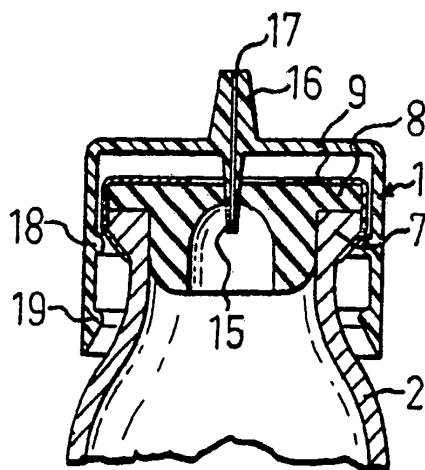
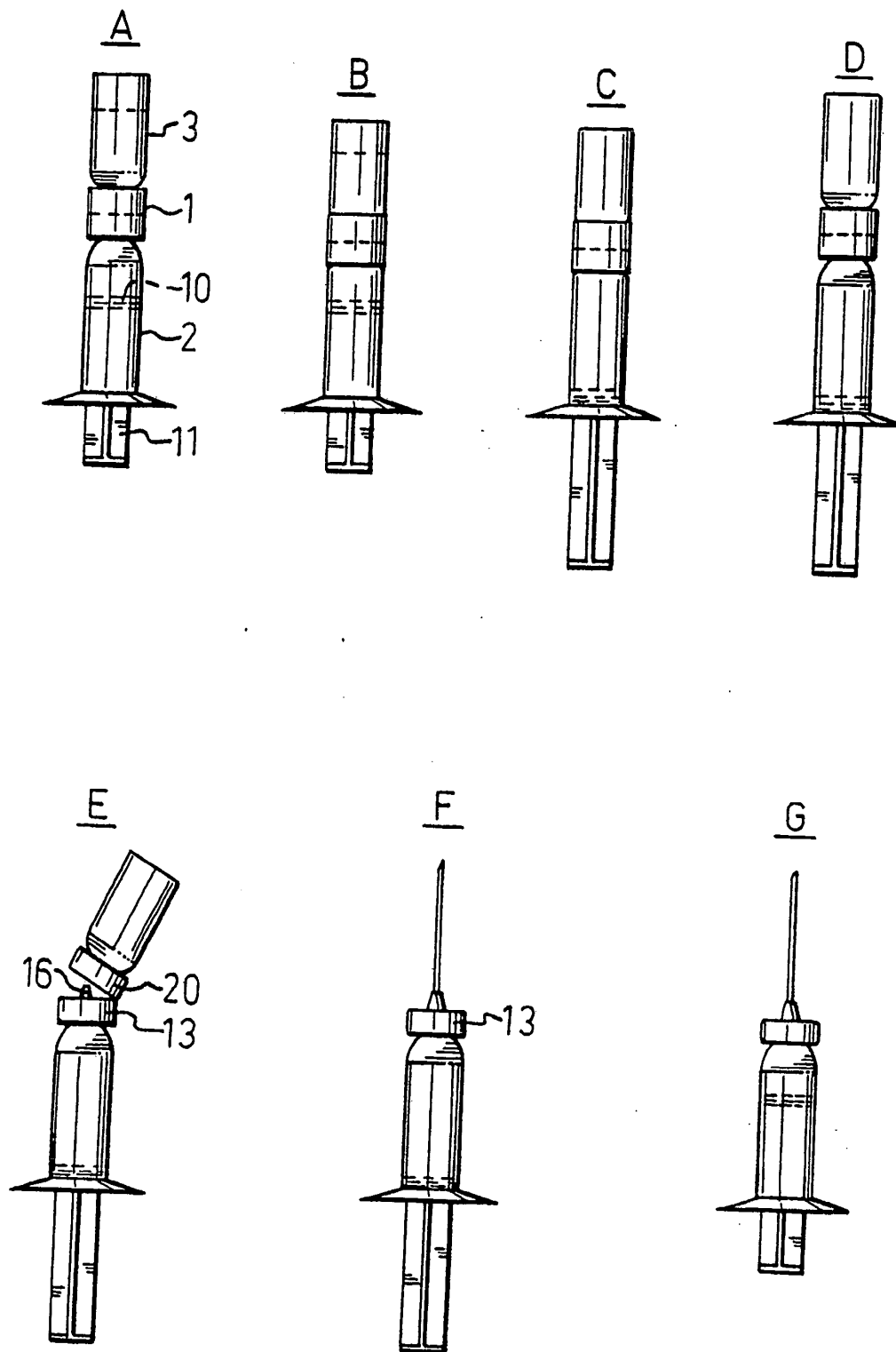


Fig.9



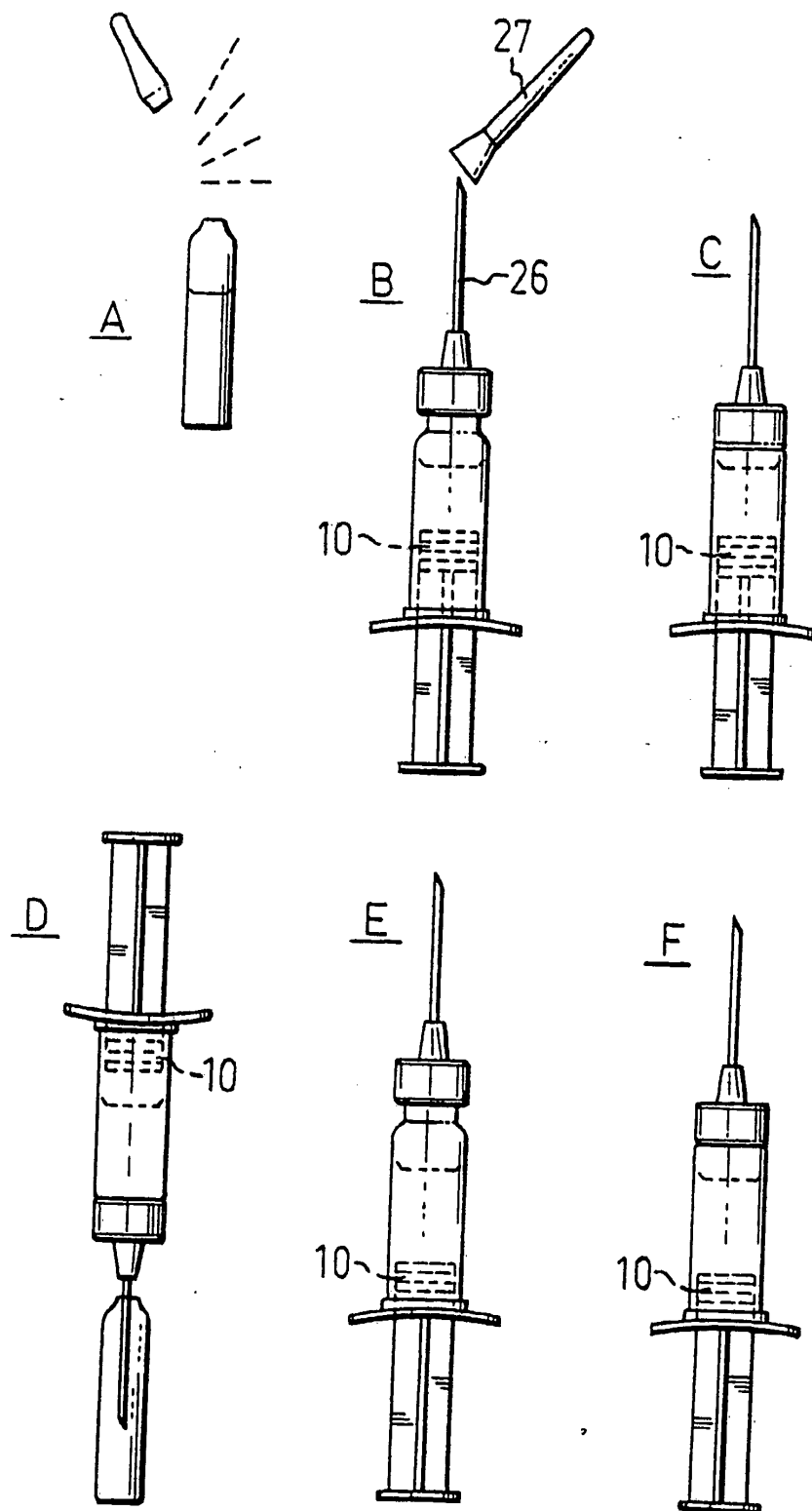
4/5

Fig.7



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Fig.10





# INTERNATIONAL SEARCH REPORT

International Application No PCT/SE87/00398

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) \*

According to International Patent Classification (IPC) or to both National Classification and IPC

A 61 M 5/00

4

## II. FIELDS SEARCHED

Minimum Documentation Searched \*

Classification System

Classification Symbols

IPC 4

US C1

A 61 J 1/00, /06; A 61 M 5/00, /18, /28, /31, /32, /34  
128: 218R, 218DA, 218M, 247, 272-272.3; 604: 56, 82,  
87-92, 200, 201, 205, 240, 403, 411-416

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched \*

SE, NO, DK, FI classes as above

## III. DOCUMENTS CONSIDERED TO BE RELEVANT \*

Category *	Citation of Document, ** with Indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
X	US, A, 3 150 661 (E J MAKI)	1,2
Y	29 September 1964	3,9
Y	DE, A, 1 766 152 (FARBENFABRIKEN BAYER)	3,9
	3 June 1971	
A	US, A, 3 826 260 (KILLINGER)	
	30 July 1974	
A	US, A, 4 084 588 (KOENIG)	1
	18 April 1978	
A	US, A, 4 516 967 (KOPFER)	
	14 May 1985	
A,P	WO, A1,86/05683 (MEDIPLAST AB)	
	9 October 1986	

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search

Date of Mailing of this International Search Report

1987-11-18

1987 -11- 2 5

International Searching Authority

Signature of Authorized Officer

Swedish Patent Office

Folke Svehsson

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